IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

OIPE JC13
APR 0 5 2004
PATENT & TRADEMARK OFFICE

Applicant(s):	ANDERSON et al.	Group Art Unit:	1743
Serial No.:	10/685,925	Examiner:	Unknown
Filed:	October 15, 2003	Docket No.:	110.01840101
		Confirmation No.:	7050
Title:	ASSAYS TO DETECT OR QUANTIFY BACTERIAL OR VIRAL PATHOGENS AND CONTAMINANTS		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

We are transmitting the following documents along with this Transmittal Sheet (which is submitted in triplicate):

X **Small entity status is entitled to be asserted in the above-identified application.**
X An itemized return postcard.
___ A Petition for Extension of Time for _ month(s) and a check in the amount of $_ for the required fee.
X An Information Disclosure Statement (2 pgs); 1449 forms (11 pgs); and copies of 93 documents cited on the 1449 forms.
___ A check in the amount of $_, representing ___.
___ A certified copy of a _ application, Serial No. _, filed _______, the right of priority of which is claimed under 35 U.S.C. §119.
___ Other: ___.
___ Amendment ___ No Additional fee is required. ___ The fee has been calculated as shown:

Fee Calculation for Claims Pending After Amendment

	Pending Claims after Amendment (1)	Claims Paid for Earlier (2)	Number of Additional Claims (1-2)	Cost per Additional Claim	Additional Fees Required
Total Claims				x $9 =	
Independent Claims				x $43 =	
One or More New Multiple Dependent Claims Presented? If Yes, Add $145 Here →					
Total Additional Claim Fees Required					

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 13-4895. Triplicate copies of this sheet are enclosed.

CERTIFICATE UNDER 37 C.F.R. §1.8: The undersigned hereby certifies that this Transmittal Letter and the paper(s), as described hereinabove, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 2 day of April, 2004.

MUETING, RAASCH & GEBHARDT, P.A.
Customer Number: 26813

By: Ann M Mueting
Name: Ann M. Mueting
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(SMALL ENTITY TRANSMITTAL UNDER RULE 1.8)

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PATENT
Docket No. 110.0184 0101

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		)		
Serial No.:	10/685,925	)	Examiner:	Unknown
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		)		
For:	ASSAYS TO DETECT OR QUANTIFY BACTERIAL OR VIRAL PATHOGENS AND CONTAMINANTS			

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with C.F.R. §§ 1.97 *et. seq.*, the materials enclosed herewith are brought to the attention of the Examiner as possibly being of interest in connection with the above-identified patent application. Per M.P.E.P. § 609, the information cited in the present Information Disclosure Statement shall not be construed to be an admission that the information is, or is considered to be, material to patentability. Consideration of each of the documents listed on the attached 1449 forms is respectfully requested. As this patent application was filed after June 30, 2003, copies of the U.S. patents and U.S. patent application publications listed on the attached 1449 forms have not been submitted. Pursuant to the provisions of M.P.E.P. §609, Applicants further request that a copy of the 1449 forms, marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

It is believed that no fee is due, as this Information Disclosure Statement is filed prior to the receipt of any Action on the merits. However, in the event a fee is due, please charge any fee or credit any overpayment to Account No. 13-4895.

The Examiner is invited to contact Applicants' Representatives at the below-listed telephone number, if they can be of any assistance during prosecution of the present application.

CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this paper is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 2 day of April, 2004.

Ann M Mueting

Name: Ann M. Mueting

April 2, 2004
Date

AMM/skd

Respectfully submitted for

ANDERSON et al.

By
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U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
		4,797,363	01/10/89	Teodorescu et al.			
		4,861,709	08/29/89	Ulitzur et al.			
		4,865,979	09/12/89	Nakano et al.			
		5,085,982	02/04/92	Keith			
		5,447,836	09/05/95	Wolber et al.			
		5,498,525	03/12/96	Rees et al.			
		5,627,024	05/06/97	Maruyama et al.			
		5,648,232	07/15/97	Squirrell			
		5,679,510	10/21/97	Ray et al.			
		5,714,312	02/03/98	Nuno Bardosa Nolasco et al.			
		5,723,330	03/03/98	Rees et al.			
		5,736,351	04/07/98	Miller et al.			
		5,773,710	06/30/98	Squirrell			
		5,798,214	08/25/98	Squirrell			
		5,824,468	10/20/98	Scherer et al.			
		5,837,465	11/17/98	Squirrell et al.			
		5,858,648	01/12/99	Steel et al.			
		5,888,725	03/30/99	Sanders			
		5,914,240	06/22/99	Sanders			
		5,918,259	06/29/99	Squirrell			
		5,985,596	11/16/99	Wilson			
		5,958,675	09/28/99	Wicks et al.			

EXAMINER	**Date Considered**

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Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
		6,090,541	07/18/00	Wicks et al.			
		6,132,983	10/17/00	Lowe et al.			
		6,165,710	12/26/00	Robinson			
		6,190,856 B1	02/20/01	Li			
		6,203,996 B1	03/20/01	Duffy et al.			
		6,265,177 B1	07/24/01	Squirrell et al.			
		6,355,445 B2	03/12/02	Cherwonogrodzky et al.			
		6,379,908 B1	04/30/02	Bodenhamer			
		6,395,504 B1	05/28/02	Trudil			
		6,395,562 B1	05/28/02	Hammock et al.			
		6,436,652 B1	08/20/02	Cherwonogrodzky et al.			
		6,473,171 B1	10/29/02	Buttry et al.			
		2001/0055780 A1	12/27/01	Cherwonogrodzky et al.			
		2002/0045234 A1	04/18/02	Squirrell et al.			
		2002/0182743 A1	12/05/02	Perkins et al.			
		2003/0027241 A1	02/06/03	Sayler et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
		0 139 143 B1	01/07/88	EP				
		0 168 933 B1	04/28/93	EP				
		CA 2 130 072	02/18/03	CA (English language abstract)				

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		EP 0 781 349 B1	01/15/03	EP				
		EP 0 940 472 A1	09/08/99	EP				
		WO 89/03878	05/05/89	PCT (English language abstract)				
		WO 90/04037	04/19/90	PCT (English language abstract)				
		WO 90/04041	04/19/90	PCT				
		WO 94/17202	08/04/94	PCT				
		WO 95/23848	09/08/95	PCT				
		WO 96/17961	06/13/96	PCT (English language abstract)				
		WO 97/22713	06/26/97	PCT				
		WO 98/47521	10/29/98	PCT				

OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)

Examiner Initial		**Document Description**
		Adams, *Bacteriophages*, Interscience Publishers, Inc., New York, 1959; cover page, title page, table of contents, 8 pgs.
		Anderson et al., "Structure of *Bacillus subtilis* Bacteriophage ϕ29 and the Length of ϕ29 Deoxyribonucleic Acid," *J. Bacteriol.*, 1966;*91*:2081-2089.
		Anderson et al., "Analysis of Bacteriophage ϕ29 Gene Function: Protein Synthesis in Suppressor-Sensitive Mutant Infection of *Bacillus subtilis*," *J. Virol.*, 1974;*13*:211-221.
		Anderson et al., "Morphogenesis of Bacteriophage ϕ29," *Bacillus subtilis and other Gram-Positive Bacteria: Biochemistry, Physiology, and Molecular Genetics*, Washington, D.C., 1993;859-867.
		"BioMag Protein A and Protein G Suspensions," datasheet, [online]. QIAGEN Ltd., UK, [retrieved on 09/30/02]. Retrieved from the Internet:<URL:http.www.qiagen.com/catalog/auto/cget.asp?p=BioMag_protein_A_protein_G>; 2 pgs.

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Examiner Initial		**Document Description**
		"Biomag System," datasheet [online]. QIAGEN Ltd., UK, [retrieved on 09/30/02]. Retrieved from the Internet:<URL:http.www.qiagen.com/catalog/auto/cget.asp?p=Biomag_system&l=en&LNK=LBROWSI...>; 2 pgs.
		Carella et al., "A Manual Bead Assay for the Determination of Absolute CD4$^+$ and CD8$^+$ Lymphocyte Counts in Human Immunodeficiency Virus-Infected Individuals," *Clin. Diagn. Lab. Immunol.*, 1995;*2*(5):623-625.
		Che et al., "Detection of *Campylobacter jejuni* in poultry samples using an enzyme-linked immunoassay coupled with an enzyme electrode," *Biosens. Bioelectron.*, 2001;*16*:791-797.
		Corbitt et al., "Adenylate kinase amplification of ATP bioluminescense for hygiene monitoring in the food and beverage industry," *Lett. Appl. Microbiol.*, 2000;*30*(6):443–447.
		Davidson et al., "Immobilization of the restriction enzymes *Hae*lll and *Hind*lll on porous silica particles via a glutaraldehyde linkage for the micro-digestion of dsDNA with analysis by capillary electrophoresis," *J. Sep. Sci.*, 2001;*24*:10-15.
		DeMarco et al., "Detection of *Escherichia coli* O157:H7 in 10- and 25-Gram Ground Beef Samples with an Evanescent-Wave Biosensor with Silica and Polystyrene Waveguides," *Journal of Food Protection*, 2002; *65*(4):596-602.
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		DiBiasio, "Swords into ploughshares: Circus reveals new investments," [retrieved on 03/24/03] Retrieved from the Internet:<URL:http://www.financeasia.com/Articles/C0ACDCF5-2719-11D6-81DD0090277E174B.cfm>; 1 pg.
		Dickson et al., "A Fast and Accurate Detection Method of *E. coli* O157:H7 in Beef," Iowa State University and Advanced Technologies, Inc., Abstract, [retrieved on 04/03/03]. Retrieved from the Internet:<URL:http://www.aati-us.com/74fld5a8-f867-4165-bfd7-9aecble248f2.cms>; 1 pg.

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		Dodson, "Salmonella Test Developer to Work at University of Illinois," Food Safety NewsLetter - Food HAACCP.com, [retrieved on 03/10/03}. Retrieved from the Internet:<URL:http://www.foodhaccp.com.memberonly/ newsletter56.htm.>; 1 pg.
		Dodson, "Quick test for bacteria," The News-Gazette, posted by News on 10:46:54 3/3/2003, [retrieved on 03/17/03]. Retrieved from the Internet:<URL: http://www.foodhaccp.com/msgboard.mv?parm_func=showmsg+parm_msgnum =1007352>; 2 pgs.
		"Dstl teams up with industry in joint venture to help protect the public from contaminated food," Press Release, 10/04/02, [retrieved on 03/24/03]. Retrieved from the Internet:<URL:http://www.dstl.gov.uk/pr/press/pr2002/04-10-02.htm>; 3 pgs.
		Dutton, "Beads and Kits for Biomagnetic Separations - Growing Need to Address Increasingly Challenging Samples," *Genetic Engineering News*, 2002;*22*(13):3 pgs.
		DYNAL Biotech, Dynabeads® Protein G, Prod. No. 100.03, 100.04, Printed 0102, Rev. no. 001, 8 pgs.
		DYNAL Biotech, Dynabeads® Protein A, Prod. No. 100.01, 100.02, Printed 0402, Rev. no. 003, 7 pgs.
		DYNAL Biotech, Dynabeads® M-280 Streptavidin, Prod. No. 112.05, 112.06, 112.16, 602.10, Printed 1201, Rev. no. 007, 9 pgs.
		Binding Capacity of Dynabeads® M-280 Streptavidin, 10/04/02; 1 pg.
		Favrin et al., "Development and Optimization of a Novel Immunomagnetic Separation-Bacteriophage Assay for Detection of *Salmonella enterica* Serovar Enteritidis in Broth," *Applied and Environmental Microbiology*, 2001;*67*(1):217-224.
		Favrin et al., "Application of a novel immunomagnetic separation-bacteriophage assay for the detection of *Salmonella enteritidis* and *Escherichia coli* O157:H7 in food," *International Journal of Food Microbiology*, 2003;*85*:63-71.

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		Giardino, "AK-phage™ Assay: An ultra rapid pathogen detection system," Food Microbiology Symposium Rapid Method Workshop, October 19-22, 2003, PowerPoint presentation, [retrieved on 02/20/04]. Retrieved from the Internet: <URL:http://www.alaskafoodiagnostic.com/default.asp?id=34.htm>; 28 pgs.
		Goding, "Production of Monoclonal Antibodies," *Monoclonal Antibodies: Principles and Practice*, Academic Press, 1986; 59-103.
		Grajewski et al., "Development of a Bacteriophage Typing System for *Campylobacter jejuni* and *Campylobacter coli*," *J. Clin Microbiol.*, 1985;*22*(1):13-18.
		Grant et al., "Improved detection of *Mycobacterium avium* subsp. *paratuberculosis* in milk by immunomagnetic PCR," *Vet. Microbiol.*, 2000;*77*:369-378.
		Griffiths, "Canadian Research Institute for Food Safety," *Research Focus, Food Safety and Security Newsletter*, February 2000:3-6.
		Grimes et al., "*In Vitro* Packaging of Bacteriophage ϕ29 DNA Restriction Fragments and the Role of the Terminal Protein gp3," *J. Mol. Biology*, 1989; *209*(1):91-100.
		Grimes et al., "Bacteriophage ϕ29 DNA Packaging," *Advances in Virus Research*, 2002;*58*:255-294.
		Harkins et al., "Rapid detection of *Salmonella*, *Listeria* and *E. coli* O157:H7 contamination in foods & food processing surfaces in less than 24 hours," Advanced Analytical Technologies, Inc., Ames, IA, Abstract, [retrieved on 04/03/03]. Retrieved from the Internet:<URL:http://www.aati-us.com/0a321962-30b5-47c4-b53b-bcc510be4c18.cms>; 1 pg.
		Hastings et al., Eds., *Bioluminescence and Chemiluminescence – Molecular Reporting with Photons*, Proceedings of the 9th International Symposium on Bioluminescence and Chemiluminescence, Woods Hole, MA, October 1996, cover page, title page, table of contents, 7 pgs.
		Hibma et al., "Infection and removal of L-forms of *Listeria monocytogenes* with bred bacteriophage," *International Journal of Food Microbiology*, 1997;*34*:197-207.

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Examiner Initial		**Document Description**
		Irwin et al., "Minimum Detectable Level of *Salmonellae* Using a Binomial-Based Bacterial Ice Nucleation Detection Assay (BIND$^{®}$)," *Journal of AOAC International*, 2000; *83*(5):1087-1095.
		Jarlov, "Phenotypic characteristics of coagulase-negative staphylococci: typing and antibiotic susceptibility," Thesis, Statens Serum Institut, Copenhagen Denmark, *APMIS Supplementum*, Munksgaard-Copenhagen, 1999;*91*(107):42 pgs.
		Kaclíková et al., "Separation of *Listeria* from cheese and enrichment media using antibody-coated microbeads and centrifugation," *J. Microbiol. Methods*, 2001;*46*(1):63-67.
		Kala et al., "Magnetic Bead Enzyme-Linked Immunosorbent Assay (ELISA) Detects Antigen-Specific Binding by Phage-Displayed scFv Antibodies that are not Detected with Conventional ELISA," *Analytical Biochemistry, Article No. AB972378*, 1997; *254*:263-266.
		Kang et al., "Screening Bovine Carcass Sponge Samples for *Escherichia coli* O157 Using a Short Enrichment Coupled with Immunomagnetic Separation and a Polymerase Chain Reaction-Based (BAX) Detection Step," *J. Food Prot.*, 2001;*64*(10):1610-1612.
		Karam et al., Eds., *Molecular Biology of Bacteriophage T4*, 1994, ASM Press, Washington, D.C., cover page, title page, table of contents, 7 pgs.
		Kerr et al., "A comparison of a monoclonal antibody-based sandwich ELISA and immunomagnetic bead selective enrichment for the detection of *Escherichia coli* O157 from bovine faeces," *J. Appl. Microbiol.*, 2001;*91*(5):933-936.
		Klausegger et al., "Gram Type-Specific Broad-Range PCR Amplification for Rapid Detection of 62 Pathogenic Bacteria," *Journal of Clinical Microbiology*, 1999;*37*(2):464-466.
		Köhler et al., "Derivation of specific antibody-producing tissue culture and tumor lines by cell fusion," *Eur. J. Immunol.*, 1976;*6*:511-519.
		Leahy, "Rapid strike on food bacteria," posted by News on 10:04:50 10/04/2002, [retrieved on 03/17/03]. Retrieved from the Internet:<URL:http://www. foodhaccp.com/msgboard. mv?parm_func=showmsg+parm+msgnum =1005289>; 1 pg.

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		Levinson et al., "Part VIII: Brief Summaries of Medically Important Organisms," *Medical Microbiology & Immunology, Examination and Board Review*, McGraw-Hill Companies, Inc., 6th Ed., 2000;414-433.
		Liu et al. "Rapid Detection of *Escherichia coli* O157:H7 Inoculated in Ground Beef, Chicken Carcass, and Lettuce Samples with an Immunomagnetic Chemiluminescence Fiber-Optic Biosensor," *Journal of Food Protection*, 2003;*66*(3):512-517.
		Loessner et al., "Construction of Luciferase Reporter Bacteriophage A511::*lux*AB for Rapid and Sensitive Detection of Viable *Listeria* Cells," *Applied and Environmental Microbiology*, 1996;*62*(4):1133-1140.
		Mullins et al., "Selective recovery of *Streptosporangium fragile* from soil by indirect immunomagnetic capture," *Microbiology*, 1995;*141*:2149-2156.
		Murphy et al., "The Use of Adenylate Kinase for the Detection and Identification of Low Numbers of Microorganisms," *Bioluminescence and Chemiluminesence, Luminescence in Medicine and Disease, Clinical Chemistry and Microbiology*, pp. 319-322.
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		Noppen et al., "Rapid, Automated Sample Processing and Detection of Numerous Bacteria Using MagNA Pure LC and the LightCycler System," Reprint from Biochemica, 2001;*3*:1-3.
		Olsvik et al., "Magnetic Separation Techniques in Diagnostic Microbiology," *Clin. Microbiol Rev.*, 1994;*7*(1):43-54.
		Park et al., "A Latex Bead-Based Flow Cytometric Immunoassay Capable of Simultaneous Typing of Multiple Pneumococcal Serotypes (Multibead Assay)," *Clin. Diagn. Lab. Immunol.*, 2000;*7*(3):486-489.
		Porter et al., "An evaluation of lectin-mediated magnetic bead cell sorting for the targeted separation of enteric bacteria," *J. Appl. Microbiol.*, 1998;*84*(5):722-732.
		"Purdue Center Aims at Preventing, Detecting Food Contamination," Newswise/Science News, posted on 9:17:08 10/21/02, [retrieved on 03/17/03]. Retrieved from the Internet:<URL:http://www.foodhaccp.com/msgboard.mv?parm_func=showmsg_parm_msgnum=1005551>; 2 pgs.

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		QuantumDot Vision, brochure, QuantumDot Corporation, Hayward, CA, March 2003;*1*(1):16 pgs.
		Ramamurthy et al., "Comparison of the sensitivity & specificity of a polyclonal versus monoclonal capture antibody based Bead ELISA for direct detection of cholera toxin from stool specimens," *Indian J. Med. Res.*, 1996;*104*:125-128.
		Rivera et al., "A new method for rapidly removing contaminating micro-organisms from porcine parvovirus or pseudorabies virus master-seed suspensions," *Vaccine*, 1993;*11*(3):363-365.
		Romahn, "Guelph Researchers Try to Make Food Safer," Jan. 3, 1999, K-W Record, C12, [retrieved on 1/19/04]. Retrieved from internet: <URL:http://131.104.232.9/fsnet/2000/1-2000/fs-01-03-00-01.txt>;2 pgs.
		Romalde et al. "Assessment of a magnetic bead-EIA based kit for rapid diagnosis of fish pasteurellosis," *J. Microbiol. Methods*, 1999;*38*:147-154.
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***Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.**

INFORMATION DISCLOSURE STATEMENT	**Atty. Docket No.:** 110.0184 0101	**Serial No.:** 10/685,925
	Applicant(s): ANDERSON et al.	**Confirmation No.:** 7050
	Application Filing Date: 10/15/03	**Group:** 1743
	Information Disclosure Statement mailed:	April 2, 2004

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